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REGULATORY REFORM

Procedural and Analytical  
Requirements in Federal  
Rulemaking

Statement of Robert P. Murphy, General Counsel



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# Regulatory Reform: Procedural and Analytical Requirements in Federal Rulemaking

I am pleased to be here today to discuss our reviews of agency compliance with a number of procedural and analytical requirements in federal rulemaking. The reviews were conducted in response to congressional concerns that agencies had not adequately considered the effects of their actions on regulated entities or worked to minimize any negative effects. The requirements that we examined are contained in a number of statutes and executive orders governing the rulemaking process, including the Administrative Procedures Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, and Executive Orders 12866 and 12612.

In brief, our congressionally requested evaluations have produced a mixed result. While they may not have been representative of all rulemakings, in some cases our work disclosed inadequate data, methodologies, or assumptions, and in other disclosed noncompliance with statutory requirements or executive orders. There are examples in which our reviews have helped ensure better adherence to applicable regulatory requirements. On the other hand, sometimes our reviews did not disclose a failure to comply with rulemaking requirements, but provided Congress with factual detail and a better understanding of the agencies' procedures and decision making. In others cases, our reviews established that the agencies were acting within allowable discretion to determine that certain requirements were inapplicable, and in others, that the requirements themselves were narrowly tailored and had little effect on rulemaking. We also found cases where regulations that were considered burdensome by the regulated community were required by the statute being implemented.

## Congressional Oversight Can Address Some Regulatory Concerns

Some of our work on regulatory issues has clearly demonstrated the value of congressional oversight of agency rulemaking. Congressional oversight can clarify issues left unclear in agencies' public statements about their rules and, on occasion, can directly result in changes to agencies' rules. The targets of that oversight can vary substantially—from the particular (and sometimes highly technical) elements of agencies' economic analyses used to support the rules, to the general public participation requirements in the rulemaking process.

## Reviews Indicate Some Agency Economic Analyses Need Improvement

A great deal of congressional attention and concern has recently been focused on the economic analyses that agencies prepare in support of their regulatory actions. Under Executive Order 12866, issued by President Clinton in September 1993, covered agencies are required to submit their "significant" rules to the Office of Management and Budget (OMB) before publishing them in the Federal Register. Agencies are also required to prepare a detailed economic analysis for any regulatory actions that are "economically significant" (e.g., have an annual effect on the economy of

\$100 million or more).<sup>1</sup> According to the executive order, the analyses should include an assessment of the costs and benefits anticipated from the action as well as the costs and benefits of "potentially effective and reasonably feasible alternatives to the planned regulation." The order also states that, in choosing among alternatives, an agency should select those approaches that maximize net benefits and "base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation."

In January 1996, OMB issued "best practices" guidance on preparing cost-benefit analyses under the order. The guidance gives agencies substantial flexibility regarding how the analyses should be prepared, but also indicates that the analyses should contain certain basic elements and should be "transparent"—disclosing how the study was conducted, what assumptions were used, and the implications of plausible alternative assumptions.

At the request of Members of Congress, we have examined agencies' economic analyses both in our reviews of selected federal rules issued by multiple agencies and in the context of particular regulatory actions. In one of our reviews, we reported that some of the 20 economic analyses from 5 agencies that we reviewed did not incorporate all of the best practices set forth in OMB's guidance.<sup>2</sup> Five of the analyses did not discuss alternatives to the proposed regulatory action, and, in many cases, it was not clear why the agencies used certain assumptions. Also, five of the analyses did not discuss uncertainty associated with the agencies' estimates of benefits and/or costs, and did not document the agencies' reasons for not doing so. We recommended that OMB's best practices guidance be amended to provide that economic analyses should (1) address all of the best practices or state the agency's reason for not doing so, (2) contain an executive summary, and (3) undergo an appropriate level of internal or external peer review by independent experts.

## Oversight of Analyses Can Result in Changes to Rules

In some cases, our congressionally-requested reviews of agencies' regulatory analyses have resulted in changes to the associated rules. For example, we reported last year on the scientific basis for the Food and Drug Administration's (FDA) proposed rule on dietary supplements

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<sup>1</sup>Similar economic analysis requirements had previously been in place under Executive Order 12291, issued by President Reagan in 1981.

<sup>2</sup>Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses (GAO/RCED-98-142, May 26, 1998).

containing ephedrine alkaloids and the agency's adherence to statutory and executive order regulatory analysis requirements.<sup>3</sup> Although the number and type of adverse event reports that FDA received warranted the agency's consideration of steps to address safety issues, we expressed concerns about the strength of some of the information FDA used to support two aspects of the proposed rule—the dosing level and duration of use limits. We concluded that FDA generally complied with the statutory and executive order requirements applicable to the rulemaking, but the economic analysis that accompanied the rule did not reflect the full range of uncertainty associated with the proposed rule. The agency did not always disclose why certain key assumptions were made or the degree of uncertainty involved in those assumptions. It also did not disclose that alternative assumptions would have had a dramatic effect on the agency's estimate of the benefits of the proposed actions. We recommended that FDA obtain additional information to support conclusions regarding the specific elements in the proposed rule before proceeding to final rulemaking. We also recommended that FDA improve the transparency of its cost-benefit analysis in its final rule. In April 2000, FDA announced that it was withdrawing certain portions of its proposed rule “because of concerns regarding the agency's basis for proposing a certain dietary ingredient level and a duration of use limit for these products.”<sup>4</sup>

In a review that we released earlier this year, we reported on the Federal Emergency Management Agency's (FEMA) plans to revise its regulations pertaining to public assistance insurance requirements.<sup>5</sup> Although the rule was economically significant, FEMA had not conducted an analysis of the expected costs and benefits of the draft regulation before submitting it to OMB for its review, and had not prepared a comprehensive analysis of other alternatives. In response to our preliminary discussions with FEMA about these issues, FEMA entered into a contract with a management consulting firm to conduct a cost-benefit analysis and to examine and assess alternative approaches. FEMA also began additional analysis of the impact of its draft regulations on small entities in response to OMB's concerns about FEMA's compliance with the Regulatory Flexibility Act. Finally, FEMA decided to issue an advance notice of proposed rulemaking before issuing the proposed rule.

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<sup>3</sup>Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids (GAO/HEHS/GGD-99-90, July 2, 1999).

<sup>4</sup>Federal Register, Vol. 65, No. 64 (Apr. 3, 2000), p. 17474.

<sup>5</sup>Disaster Assistance: Issues Related to the Development of FEMA's Insurance Requirements (GAO/GGD/OGC-00-62, Feb. 25, 2000).

Oversight of Analyses Can  
Clarify Agencies' Actions,  
Answer Questions

In some cases, we are asked to review and comment on agencies' rulemaking approaches without specific reference to Executive Order 12866. For example, in response to a requirement in the Balanced Budget Act of 1997, we issued a report in February 1998 evaluating a Health Care Financing Administration (HCFA) proposed rule describing revisions to fee schedules used to pay physicians in the Medicare program.<sup>6</sup> We concluded that the methodology that HCFA used to develop the fee schedules was generally acceptable, but needed some modifications. In June 1998, HCFA published its revised proposal, and published its final rule in November 1998. Several Members of Congress then asked us to monitor and report on HCFA's new methodology. In a report issued last year, we concluded that the new methodology was an acceptable approach, and that it responded to several concerns we had with the agency's original approach.<sup>7</sup> Nevertheless, we said that certain questions about the data and methodology needed to be addressed before full implementation. We recommended that the Administrator of HCFA take several actions to address our concerns.

Some of our reviews of agencies' specific regulatory analyses have clarified how the associated rules were developed or answered other questions posed by congressional requesters, but did not conclude that the agencies actions were deficient. These kinds of information-gathering efforts are often crucial to ensure that Congress and the public understand how regulations are developed, and the strength of the data, methodology, and assumptions that underlie the rules. For example, in January 1998, we reported on our review of the Environmental Protection Agency's (EPA) final rule that limited sulfur dioxide emissions from the Navajo Generating Station by approximately 90 percent.<sup>8</sup> Specifically, we discussed the effect of changes between the proposed and final rule on emissions reductions and associated costs, how the agency determined the expected level of visibility improvements, and how the agency estimated the monetary value of those improvements.

In January 1999, we explained why there were significant differences between EPA's and the industry's cost estimates of EPA's proposed

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<sup>6</sup>Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments (GAO/HEHS-98-79, Feb. 27, 1998).

<sup>7</sup>Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

<sup>8</sup>Air Pollution: Estimated Benefits and Costs of the Navajo Generating Station's Emissions Limits (GAO/RCED-98-28, Jan. 27, 1998).

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pretreatment standards for industrial laundries.<sup>9</sup> We also discussed how EPA estimated the benefits of the proposed rule, uncertainties associated with the accuracy of its estimates, and how EPA's analysis supported the agency's belief that it had chosen the least costly, most cost-effective, or least burdensome regulatory alternative.

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### Agency Explanations for Use of the APA's "Good Cause" Exception Were Sometimes Unclear

The most long-standing and broadly applicable federal rulemaking requirements are in the Administrative Procedure Act (APA) of 1946. Among other things, the APA generally requires that agencies publish a notice of proposed rulemaking (NPRM) in the Federal Register. After giving "interested persons" an opportunity to comment on the proposed rule, and after considering the public comments, the agency may then publish the final rule. However, the APA says that the notice and comment procedures generally do not apply when an agency finds, for "good cause," that those procedures are "impracticable, unnecessary, or contrary to the public interest."<sup>10</sup> When agencies use the good cause exception, the act requires that they explicitly say so and provide a rationale for the exception's use when the rule is published in the Federal Register.

In August 1998, we reported that about half of the 4,658 final regulatory actions published in the Federal Register during 1997 were issued without NPRMs.<sup>11</sup> Although most of the final actions without NPRMs appeared to involve administrative or technical issues with limited applicability, some were significant actions, and 11 were economically significant. Some of the explanations that the agencies offered in the preambles to their rules for using the good cause exception were not clear. For example, in several cases, the preambles said that an NPRM was "impracticable" because of statutory or other deadlines that had already passed by the time the rules were issued. In other cases, the agencies asserted in the preambles that notice and comment would delay rules that were, in some general way, in the "public interest." For example, in one such case, the agency said it was using the good cause exception because the rule would "facilitate tourist and business travel to and from Slovenia," and therefore delaying the rule to allow for public comments "would be contrary to the public interest." In another case, the agency said that soliciting public comments on the

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<sup>9</sup>Water Pollution: Proposed Pretreatment Standards for Industrial Laundries (GAO/RCED-99-42R, Jan. 20, 1999).

<sup>10</sup>The APA also provides exceptions to the NPRM requirement for certain categories of regulatory action (e.g., rules dealing with military or foreign affairs). It also says the notice and comment procedures do not apply to interpretive rules; general statements of policy; or rules of agency organization, procedure, or practice.

<sup>11</sup>Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules (GAO/GGD-98-126, Aug. 31, 1998).

rule was "contrary to the public interest" because the rule authorized a "new and creative method of financing the development of public housing."

When agencies publish final rules without NPRMs, the public's ability to participate in the rulemaking process is limited. Also, several of the regulatory reform requirements that Congress has enacted during the past 20 years use as their trigger the publication of an NPRM. Therefore, it is important that agencies clearly explain why notice and comment procedures are not followed. We recommended in our report that OMB notify executive departments and agencies that (1) their explanations in the preambles to their rules should clearly explain why notice and comment was impracticable, unnecessary, or not in the public interest, and (2) that OMB would, as part of its review of significant final rules, focus on those explanations.

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### Compliance With Congressional Review Act Requirements Has Been Inconsistent

We have also had an effect on agencies' rulemaking actions as a result of our responsibilities under the Congressional Review Act (CRA). For example, under the CRA, before a final rule can become effective it must be filed with the Congress and GAO. However, in 1998, we reported that several hundred final rules had been published in the Federal Register but had not been submitted to us. We then worked with the agencies and OMB to correct the situation, and now virtually all of the rules that should have been submitted are being filed.

A related problem has been determining whether certain documents constitute "rules" that must be submitted in accordance with the CRA. For example, in one case, EPA claimed that its interim guidance for investigating complaints under title VI of the Civil Rights Act of 1964 was not a "rule," and therefore did not have to be submitted to the Congress and GAO before it could become effective. We concluded that the document was a rule because it clearly affected the rights of nonagency parties, and therefore had to be submitted pursuant to the CRA's requirements.

Another problem related to the CRA has been the failure of some agencies to delay the effective dates of their major rules for 60 days as required by section 801(a)(3)(A) of the Act. Agencies were not budgeting enough time into their regulatory timetable to allow for the delay and were misinterpreting the "good cause" exception to the 60-day delay period found in section 808(2) of the Act. We again worked with the agencies and, as a result, agencies have been much less likely to erroneously avoid the required 60-day delay.



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## Some Rulemaking Requirements Are Unspecific or Apply to Few Rules

In each of the examples that I have cited, we were able to compare the agencies' rulemaking actions to statutory or executive order requirements and determine whether the agencies' actions satisfied the requirements. However, some of the concerns that have been expressed about agencies' compliance with rulemaking requirements appear traceable to the requirements themselves. Some are not specific, giving the agencies broad discretion to determine whether the mandated actions are applicable to their rules. Other requirements apply to few rules and/or require little new analysis for the rules to which they are applicable.

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## Regulatory Flexibility Requirements Need Clarification

The Regulatory Flexibility Act (RFA) of 1980, enacted in response to concerns about the effect that federal regulations can have on small entities, is an example of a broadly-based rulemaking requirement. Under the RFA, an agency must prepare an initial regulatory flexibility analysis at the time proposed rules are issued unless the head of the agency determines that the proposed rule would not have a "significant economic impact upon a substantial number of small entities." The act also requires agencies to ensure that small entities have an opportunity to participate in the rulemaking process, and requires the Chief Counsel of the Small Business Administration's (SBA) Office of Advocacy to monitor agencies' compliance with the Act. The RFA was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act to, among other things, require that EPA and the Occupational Safety and Health Administration convene advocacy review panels before publishing an initial regulatory flexibility analysis.

We have reported on the implementation of the RFA on several occasions in the past, and a recurring theme in our reports is the varying interpretation of the RFA's requirements by federal agencies. For example, in 1991, we reported that each of the four federal agencies that we reviewed had a different interpretation of key RFA provisions.<sup>12</sup> The report pointed out that the RFA provided neither a mechanism to enforce compliance with the act nor guidance on implementing it. We recommended that Congress consider amending the RFA to require that SBA develop criteria for whether and how federal agencies should conduct RFA analyses.

In 1994 we examined the 12 SBA annual reports on agencies' RFA compliance that had been issued since 1980.<sup>13</sup> The reports indicated that

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<sup>12</sup>Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments (CAO/HRD-91-16, Jan. 11, 1991).

<sup>13</sup>Regulatory Flexibility Act: Status of Agencies' Compliance (GAO/GGD-94-105, Apr. 27, 1994).



agencies' compliance with the RFA varied widely from one agency to another, and that some agencies' compliance varied over time. We noted that the RFA does not expressly authorize SBA to interpret key provisions of the statute, and does not require SBA to develop criteria for agencies to follow in reviewing their rules. As a result, different rulemaking agencies were interpreting the statute differently. We said that if Congress wanted to strengthen the implementation of the RFA it should consider amending the act to provide SBA with clearer authority and responsibility to interpret the RFA's provisions and require SBA to develop criteria on whether and how agencies should conduct RFA analyses.

We essentially repeated this recommendation in our 1998 report on the implementation of the small business advocacy review panel requirements, noting that Congress should provide SBA or another entity with interpretive authority and responsibility.<sup>14</sup> We said that the lack of clarity regarding whether EPA should have convened review panels for its two proposed rules on ozone and particulate matter was traceable to the lack of agreed-upon government criteria for whether a rule has a "significant economic impact on a substantial number of small entities" under the RFA. Similarly, we concluded in our 1999 report on the review requirements in section 610 of the RFA that the agencies we reviewed differed in their interpretation of those review requirements.<sup>15</sup> We said that if Congress was concerned about these varying interpretations it might wish to consider clarifying those provisions.

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### Federalism Executive Order Had Little Effect on Rulemaking

Executive Order 12612 on "Federalism," issued by President Reagan in 1987, also gave federal agencies broad discretion to determine its applicability. The executive order required the head of each federal agency to designate an official to be responsible for determining which proposed policies (including regulations) had "sufficient federalism implications" to warrant preparation of a federalism assessment. If the designated official determined that such an assessment was required, it had to accompany any proposed or final rule submitted to OMB for review.

We examined the preambles of more than 11,000 final rules that federal agencies issued between April 1996 and December 1998 to determine how often they mentioned the executive order and how often the agencies

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<sup>14</sup>Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements (GAO/GGD-98-36, Mar. 18, 1998).

<sup>15</sup>Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary (GAO/GGD-99-55, Apr. 2, 1999).

indicated that they had prepared a federalism assessment.<sup>16</sup> Our work indicated that Executive Order 12612 had relatively little visible effect on federal agencies' rulemaking actions during this time frame. The preambles to only 5 of the more than 11,000 rules indicated that the agencies had conducted a federalism assessment.

Most of these rules were technical or administrative in nature, but 117 were economically significant rules. However, the agencies prepared a federalism assessment for only one of these economically significant rules. The lack of assessments for these rules is particularly surprising given that the agencies had previously indicated that 37 of the rules would affect state and local governments, and said that 21 of them would preempt state and local laws in the event of a conflict.

Federal agencies had broad discretion under Executive Order 12612 to determine whether a proposed policy has "sufficient" federalism implications to warrant the preparation of a federalism assessment. Some agencies have clearly used that discretion, to establish an extremely high threshold. For example, in order for an EPA rule to require a federalism assessment, the agency's guidance said that the rule must, among other things, have an "institutional" effect on the states (not just a financial effect), and affect all or most of the states in a direct, causal manner. Under these standards, an EPA regulation that has a substantial financial effect on all states, but does not affect the "institutional" role of the states, would not require a federalism assessment.

Executive Order 12612 was revoked by President Clinton's Executive Order 13132 on "Federalism," which was issued August 4, 1999, and took effect on November 2, 1999. Like the old executive order, the new order provides agencies with substantial flexibility to determine which of their actions have "federalism implications" and, therefore, when they should prepare a "federalism summary impact statement."

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## UMRA Had Little Effect on Rulemaking

The Unfunded Mandates Reform Act (UMRA) is another example of a regulatory requirement that has had little effect on agency rulemaking. For example, title II of UMRA generally requires covered federal agencies to prepare written statements containing specific information for any rule for which a proposed rule was published that includes a federal mandate that may result in the expenditure of \$100 million or more in any 1 year by state, local, and tribal governments, in the aggregate, or the private sector.

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<sup>16</sup>Federalism: Previous Initiatives Have Had Little Effect on Agency Rulemaking (GAO/T-GGD-99-31, June 30, 1999).

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The statute defined a "mandate" as not including conditions imposed as part of a voluntary federal program or as a condition of federal assistance.

We examined the implementation of title II of UMRA during its first 2 years and concluded that it appeared to have only limited direct impact on agencies' rulemaking actions.<sup>17</sup> Most of the economically significant rules promulgated during that period were not subject to the act's requirements for a variety of reasons (e.g., no proposed rule, or the mandates were a condition of federal assistance or part of a voluntary program). There were only two rules without an UMRA written statement that we believed should have had one (EPA's proposed national ambient air quality standards for ozone and particulate matter), but even in those rules we believed that the agency had satisfied the substantive UMRA written statement requirements. Also, title II contains exemptions that allowed agencies not to take certain actions if they determined that they were duplicative or not "reasonably feasible." The title also required agencies to take certain actions that they already were required to take or had completed or that were already under way.

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## Agencies Sometimes Have Little Rulemaking Discretion

In some cases, concerns expressed by regulated entities about burdensome regulations are traceable to the statutes underlying the regulations, rather than a failure of the agency to comply with rulemaking requirements. For example, in November and December 1996, we reported what officials from 15 private sector companies said were the federal regulations that were most problematic for their businesses.<sup>18</sup> Our reports also listed responses from the 19 federal agencies that issued the regulations underlying the 125 company concerns. In about one-quarter of the cases, the agencies indicated that the companies' concerns were, at least in part, attributable to statutory requirements underlying their regulations.

We analyzed the particular statutes in question and, in a January 1999 report, concluded that the statutes underlying about half of the concerns gave the rulemaking agencies no discretion in establishing the regulatory requirements at issue; the statutes underlying most of the other concerns gave the agencies only some discretion.<sup>19</sup> In cases where the underlying

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<sup>17</sup>Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions (GAO/GGD-98-30, Feb. 4, 1998).

<sup>18</sup>Regulatory Burden: Measurement Challenges and Concerns Raised by Selected Companies (GAO/GGD-97-2, Nov. 18, 1996); and Regulatory Burden (GAO/GGD-97-26R, Dec. 11, 1996).

<sup>19</sup>Regulatory Burden: Some Agencies' Claims Regarding Lack of Rulemaking Discretion Have Merit (GAO/GGD-99-20, Jan. 8, 1999).

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statute is the source of regulatory burden, regulatory reform initiatives focused on the agencies (e.g., cost-benefit analysis requirements) are unlikely to have much direct effect on the burden that those agencies impose.

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## Congress Needs Assistance to Perform Regulatory Oversight

In summary, Madam Chairwoman, oversight alone of the regulatory process cannot, as we have learned, change agency behavior where the underlying statutes and executive orders do not clearly compel desired policies, procedures, or results. On the other hand, the examples of agency regulations that we have reviewed also demonstrate that congressional oversight can be an effective approach to ensure that agencies' rules are carefully developed and permit participation by the public in the rulemaking process. The examples also illustrate the difficulties involved in that endeavor. Agencies' rules are often highly technical, and the data, methodologies, scientific studies, and economic analyses that agencies use to develop those rules are frequently voluminous and extremely difficult to understand. The subject matter involved in these rules ranges from the health effects of environmental and occupational contaminants to the rates at which physicians are paid in the Medicare program. Therefore, it is not surprising that there are proposals to establish an independent source of analysis to evaluate agencies' development of significant regulations.

Although Congress could, theoretically, ask the agencies themselves to provide the information they need for oversight, the agencies are hardly an unbiased source of information about their own rules. Although OMB reviews every significant rule covered by Executive Order 12866 and has a wealth of expertise on rulemaking issues, its primary mission is to support the policies and goals of the President. As we said last year in our analysis of OMB's reports on the costs and benefits of all federal rules, OMB cannot realistically be expected to alter or dispute the administration's own estimates of regulatory costs and benefits in a report to Congress.<sup>20</sup>

Therefore, if Congress wants an independent assessment of regulatory costs and benefits, it should consider assigning that responsibility to an organization outside of the executive branch. As the examples that I previously cited illustrate, Congress has, on an occasional basis, requested that we perform that function. Legislation that was recently passed by the Senate, and other proposals introduced by you, Madam Chairwoman, and others in the House, would regularize that analytic responsibility. While

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<sup>20</sup>Regulatory Accounting: Analysis of OMB's Reports on the Costs and Benefits of Federal Regulation (GAO/GGD-99-59, Apr. 20, 1999).

we stand ready to assist Congress in carrying out its oversight responsibility, our ability to successfully do so will depend on (1) the scope of the analysis contemplated, (2) the number of requests that we receive, (3) the time allotted to perform the reviews, and (4) the resources that we are given to accomplish the tasks involved. These subjects are not strictly the focus of this hearing, but we would be happy to meet with Members and staff of the Subcommittee to discuss this possible legislation.

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Madam Chairwoman, this completes my prepared statement. I would be pleased to answer any questions.



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